Individual Safety Report

3198187-4-00-01

Approved by FDA on 12/02/93

Mfr report # 9837159

UF/Dist report #

FDA Use Only

"+" indicates item continued

A. Patient Information

1. Patient identifier	2. Age at time of event: 85 YRS or Date of Birth:	3. Sex	4. Weight
[redacted] in confidence		☐ Female ☒ Male	UNK lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)

☐ death ____ (mo/day/yr)
☐ life-threatening
☒ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☒ required intervention to prevent permanent impairment/damage
☐ other: ____

3. Date of event (mo/day/yr): 10/-/98

4. Date of this report (mo/day/yr): 02/10/99

5. Describe event or problem

THIS IS A FOLLOW-UP REPORT BASED ON INFORMATION RECEIVED BY PFIZER ON 26JAN99. THE INITIAL REPORT WAS SUBMITTED ON 16NOV98.
A PHYSICIAN (SON-IN-LAW OF THE PATIENT) REPORTS THAT AN 86-YEAR-OLD MALE PATIENT, WHO WAS PRESCRIBED ZOLOFT (SERTRALINE) FOR DEPRESSION, POSSIBLY 50MG/DAY, HAD AN ACCIDENTAL FALL IN HIS HOUSE. CONCOMITANT THERAPY INCLUDES COUMADIN (WARFARIN SODIUM). THE PATIENT'S DAUGHTER NOTICED THAT THE PATIENT WAS "SPACEY" AND THAT HE HAD SLURRED SPEECH. THE PATIENT WAS TAKEN TO THE EMERGENCY ROOM, WHERE THE ATTENDING PHYSICIAN FOUND THAT THE PATIENT WAS BLEEDING INTERNALLY WHERE HE HAD FALLEN. THE PATIENT WAS ADMITTED AND STAYED FOR ONE WEEK UNDER CLOSE SUPERVISION. THE PHYSICIAN DID NOT KNOW THE PATIENT'S COUMADIN LEVELS BEFORE OR AFTER THE INITIATION OF ZOLOFT; HOWEVER, HE ATTRIBUTED THE BLEEDING TO "ZOLOFT INDUCED COUMADIN LEVEL."
IN FOLLOW-UP, THE PATIENT'S PSYCHOLOGIST PROVIDED ADDITIONAL INFORMATION.
THIS CURRENTLY 86 YEAR OLD RETIRED DENTIST, CHRONICALLY ANTICOAGULATED ON COUMADIN FOR ATRIAL FIBRILLATION BEGAN ZOLOFT 25 MG/DAY FOR DEPRESSION ON 25AUG98. THE DOSE WAS GRADUALLY INCREASED TO 75 MG/DAY THEN TO 100 MG/DAY ON 13OCT98. HIS MEDICAL HISTORY INCLUDES USAGE +

6. Relevant tests/laboratory data, including dates

OCT98: EIF X-RAY - NEGATIVE FOR FRACTURE

20OCT98: PA AND LATERAL OF THE CHEST - QUESTIONABLE TRACE OF VENOUS CONGESTION, SMALL PLEURAL EFFUSION AND LEFT LOWER LOBE CONSOLIDATION WHICH MAY REPRESENT ATELECTASIS OR INFILTRATE.

20OCT98: CT OF THE ABDOMEN AND PELVIS - LEFT PSOAS HEMATOMA OF MODERATE SIZE, WHICH CONTAINED AREA OF LIQUEFACTION. THERE IS STRANDING WITH +

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)

SOCIAL HISTORY:
- LIVES WITH HIS WIFE, NEGATIVE FOR TOBACCO USE, RARE ALCOHOL USE.
FAMILY HISTORY:
- MOTHER DIED AT 65 OF CORONARY ARTERY DISEASE.
- SON RECENTLY DIAGNOSED WITH A BRAIN TUMOR.
HEARING AIDES:
- BILATERALLY
NO KNOWN ALLERGIES
HYPERTENSION +

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
1 ZOLOFT TABLETS
2 COUMADIN Cont.

2. Dose, frequency & route used
1 100.00 MG TOTAL DAILY ORAL
2 UNKNOWN

3. Therapy dates (if unknown, give duration) from/to (or best estimates)
1 08/25/98 - 10/19/98
2 UNKNOWN - 10/20/98

4. Diagnosis for use (indications)
1 DEPRESSION
2 ATRIAL FIBRILLATION

5. Event abated after use stopped or dose reduced
1 ☒ yes ☐ no ☐ doesn't apply
2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
1 UNKNOWN
2 UNKNOWN

7. Exp. date (if known)
1 UNKNOWN
2 UNKNOWN

8. Event reappeared after reintroduction
1 ☐ yes ☐ no ☒ doesn't apply
2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)
N/A

10. Concomitant medical products and therapy dates (exclude treatment of event)
LASIX — UNKNOWN - 10/20/98
K-DUR — UNKNOWN - 10/20/98

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)
PFIZER REGULATORY SAFETY
PFIZER PHARMACEUTICALS
235 EAST 42 STREET
NEW YORK, N.Y. 10017
U.S.A

DSS
FEB 16 1999
ADVERSE EVENT REPORTING SYSTEM

2. Phone number: 212-573-3129

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☒ health professional
☐ user facility
☒ company representative
☐ distributor
☐ other

4. Date received by manufacturer (mo/day/yr): 01/26/99

5. (A) NDA # NDA #19-639
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #
N/A

7. Type of report (check all that apply)
☐ 5-day ☒ 15-day
☐ 10-Day ☐ periodic
☐ initial ☒ follow-up # 1

8. Adverse event term(s)
DIZZINESS
ANOREXIA
CONSTIPATION
SOMNOLENCE
CONGESTIVE HEART FAILURE
MALAISE
PAIN
HEMORRHAGE
DRUG INTERACTION - SERTRALINE COUMADIN

9. Mfr. report number: 9837159

RECEIVED
FEB 12 1999
BY: ____

E. Initial reporter

1. Name, address & phone #
[redacted], M.D.
UNKNOWN
Tel. - UNKNOWN

2. Health professional? ☒ yes ☐ no

3. Occupation: PHYSICIAN

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

Individual Safety Report

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
3 PERCOCET
4

2. Dose, frequency & route used
3 UNKNOWN
4

3. Therapy dates (if unknown, give duration) from/to (or best estimates)
3 10/--/98 - 10/--/98
4

4. Diagnosis for use (indications)
3 PAIN
4

5. Event abated after use stoped or dose reduced
3 ☒ yes ☐ no ☐ doesn't apply
4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
3 UNKNOWN
4

7. Exp. date (if known)
3 UNKNOWN
4

8. Event reappeared after reintroduction
3 ☐ yes ☐ no ☒ doesn't apply
4 ☐ yes ☐ no ☐ doesn't apply

DSS

FEB 16 1999

ADVERSE EVENT REPORTING SYSTEM

RECEIVED
FEB 12 1999
BY:_____

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9837159

23OCT98: AFEBRILE

23OCT98: SPUTUM SAMPLE - GRAM NEGATIVE RODS, E COLI 3+, CIPROFLOXACIN SENSITIVE.

23OCT98: RIGHT UPPER QUADRANT ULTRASOUND - GALLBLADDER FULL OF SLUDGE WITH NO BILIARY DILATATION, A NORMAL LIVER, LEFT PSOAS HEMATOMA THAT RESEMBLED A HEMATOMA OF THE GALLBLADDER, THERE WAS NO ASCITES.

LABORATORY TESTS:
20OCT98: HEMOGLOBIN 7.7
HEMATOCRIT 23.6
PT 25.9
INR 4.6
PTT 60
PLATELETS 265
BUN 53
CREATININE 1.2
WBC 15.0
76% SEGS
4% BANDS
4% LYMPHS
16% MONOS
SODIUM 141
POTASSIUM 3.4
CHLORIDE 102
BICARBONATE 31
GLUCOSE 126
GUIAC NEGATIVE

20OCT98 VITAL SIGNS:
TEMPERATURE 36.6 DEGREES CELSIUS
PULSE 76
RESPIRATIONS 18
BLOOD PRESSURE 120/54
(DURING THE PATIENT'S HOSPITAL STAY, HE REMAINED RELATIVELY NORMOTENSIVE. AT DISCHARGE BLOOD PRESSURE WAS 121/55.)

21OCT98: PT 17.7
INR 2.2
PTT 44
BUN 46.7

22OCT98: COAGULOPATHY REVERSED
BUN 39
CREATININE 0.8

INITIAL LIVER FUNCTION TESTS (LFTS):
TOTAL BILI 3.5
DIRECT BILI 0.5
GAMMA GG 4
ACUTE HEPATITIS PROFILE NEGATIVE
HBS ANTIGEN NEGATIVE
HB CORE ANTIBODY NEGATIVE
HEPATITIS A AND C NEGATIVE

FOLLOW-UP LFTS:
TOTAL BILI 7.9
DIRECT BILI 3.8
ALKALINE PHOSPHATASE 173
AST 78
ALT 61

LIVER FUNCTION TESTS 26OCT98:
SHOWED A DECREASED IMPROVEMENT OF BILIRUBIN LEVELS AND A MILD INCREASE IN ALKALINE PHOSPHATASE.

LABORATORY VALUES AT THE TIME OF DISCHARGE:
HEMATOCRIT 37.2
TSH 0.4
FERRITIN 2,005
SERUM IRON 15
TIBC 145

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9837159

ACUTE HEPATITIS PROFILE A, B AND C NEGATIVE
ALKALINE PHOSPHATASE 232
AST 48
CHOLESTEROL 160
TOTAL BILI 6.7
DIRECT BILI 3.24.

B7. OTHER RELEVANT HISTORY - Continued

ATRIAL TACHYCARDIA
ESOPHAGEAL DIVERTICULA
DYSPHAGIA
CERVICAL SPONDYLOSIS
KIDNEY STONES:
- FIVE EPISODES IN THE PAST
CHRONIC RIGHT FOOT EDEMA:
- SECONDARY TO AN ATHLETIC INJURY.
BALANCE PROBLEMS

E1. NAME AND ADDRESS OF REPORTER - Continued

[redacted] MD
[redacted] MEDICAL CENTER, DEPT. OF PSYCHIATRY
[redacted] ST.,
[redacted]
Tel. - [redacted]

G8. ADVERSE EVENT TERMS - Continued

ACCIDENTAL FALL
ARRHYTHMIA
ASTHENIA
SPEECH DISORDER
HALLUCINATIONS
WEIGHT LOSS
LIVER FUNCTION TESTS ABNORMAL
COAGULATION DISORDER
ATAXIA
HYPERGLYCEMIA
LAB TEST ABNORMAL
RETROPERITONEAL HEMORRHAGE
OLIGURIA
NPN INCREASED
JAUNDICE
INFECTION BACTERIAL
SERUM IRON INCREASED
VASCULAR DISORDER

On 23Oct98, these tests were followed up by a right upper quadrant ultrasound which revealed the gallbladder to be full of sludge with no biliary dilatation, a normal liver, left psoas hematoma that resembled a hematoma of the gallbladder, there was no ascites. Liver function tests performed on 26Oct98 showed a decreased improvement of bilirubin levels and a mild increase in alkaline phosphatase. During the patient's hospital stay, he remained relatively normotensive. At the time of discharge, his blood pressure was 121/55. Other laboratory values at the time of discharge revealed Hematocrit 37.2, TSH 0.4, Ferritin 2,005, serum iron 15, TIBC 145. Acute hepatitis profile A, B and C negative, alkaline phosphatase 232, AST 48, cholesterol 160, total bili 6.7, direct bili 3.24. On 27Oct98 at the time of discharge, the patient was ambulating well with assistance, without oxygen requirement, and was sent home on the following medications: Lasix 80 mg (one tablet/day), K-Dur 20 mEq (two tablets/day), baby aspirin 81 mg (one tablet/day), Cipro (ciprofloxacin) 500 mg (one tablet/twice a day for ten days) and docusate 100 mg (one tablet/twice a day). Discharge diagnoses include prerenal azotemia, congestive heart failure and liver enzyme abnormalities. Neither the Zoloft nor Coumadin was restarted.